DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

The Department of Health and Human Services (HHS) is the Federal Government's principal agency charged with protecting the health of all Americans and providing essential human services. HHS responsibilities include: Medicare, Medicaid, support for public health preparedness and emergency response, biomedical research, substance abuse and mental health treatment and prevention, assurance of safe and effective drugs and other medical products, protection of our Nation's food supply, assistance to low income families, the Head Start program, services to older Americans, and direct health services delivery.

These programs constitute a substantial portion of the priorities of the federal government, and, as such, the HHS budget represents almost a quarter of all federal outlays, and the Department administers more grant dollars than all other agencies combined.

Since assuming the leadership of HHS this year, Secretary Kathleen G. Sebelius has sought to prioritize efforts to prepare the country for H1N1 influenza, enhance security of the nation's food supply, implement regulation of tobacco, stop the spread of HIV/AIDS and ensure that those affected get the care and support they need, and successfully build the country's healthcare infrastructure through distribution of $167 billion in funding from the American Recovery and Reinvestment Act of 2009. Further, the Secretary has worked closely with the President on the Administration's efforts to enact meaningful reform of the country's health care system, and the Department will focus considerable effort on implementation of health care reform once passed by the Congress.

The Department's regulatory priorities in the upcoming fiscal year reflect the above goals, and include:

Tobacco Regulation

Each year in the United States, over 440,000 people die as a result of cigarette smoking. This represents one in every five deaths in adults. Reducing our nation's tobacco use will save lives, reduce health care costs, and help reduce suffering from heart and lung diseases, cancer, and other tobacco-related illnesses. As directed by the Family Smoking Prevention and Tobacco Control Act, the Secretary would re-establish the bulk of the provisions of the August 1996 final rule restricting access to and promotion of tobacco products to minors when many adult smokers begin their tobacco use habits.

Food Safety

The Department is committed to making dramatic improvements in our food safety system. These efforts are guided in part by the recent findings of the President's Food Safety Working Group which adopted a public-health approach based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery if prevention fails. The goal of this new agenda is to shift emphasis away from mitigating public health harm by removing unsafe products from the market place, to a new overriding objective — preventing harm by keeping unsafe food from entering commerce in the first place. Progress has already begun on this new strategy. One example is the recent egg safety rule, which requires science-based measures to prevent *Salmonella Enteritidis* contamination of shell eggs at the farm, as well as safe handling temperature controls throughout the distribution chain. We intend to continue this focus on prevention with upcoming rules on produce safety and Good Manufacturing Practices modernization. The Department also looks forward to continuing work with the Congress to transform our nation's approach to food safety and strengthen our ability to prevent foodborne illness.

Mental Health Parity

Congress passed and the President signed legislation in October of 2008 that was a major step forward in improving access to mental health and substance abuse services for those who need them by requiring that all financial requirements and treatment limitations applicable to mental health and substance use disorders are no more restrictive than those requirements and limitations placed on physical benefits. Critical to the implementation of the law is the issuance of regulations to help employers and insurers understand what is required of them. The Secretary has directed the Centers for Medicare & Medicaid Services (CMS) to work with the Departments of Treasury and Labor to craft these regulations so as to guide employers and insurers on how to implement this statute and meet the important goal of furthering the integration of mental health and substance abuse services into primary health care.

Medicare Modernization

The Regulatory Plan highlights three final rules that would adjust payment amounts under Medicare for physicians' services, hospital inpatient and hospital outpatient services for fiscal year 2011. These new payment rules reflect continuing experience with regulating these systems, and will implement modernizations to ensure that the Medicare program best serves its beneficiaries, fairly compensates providers, and remains fiscally sound.

Healthcare Information Technology

Broad use of electronic health records has the potential to improve health care quality, prevent medical errors, increase the efficiency of care provision and reduce unnecessary health care costs, increase administrative efficiencies, decrease paperwork, and improve population health. Towards achieving these benefits, the Department will promulgate a proposed rule that would provide financial incentives to certain providers that meaningfully implement electronic health records, and an interim final rule that sets standards for such records that will enhance their interoperability, functionality, and utility.

Additionally, the Department will issue a proposed rule to implement privacy provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act that will strengthen privacy and security protections that govern how health information is used and disclosed in the face of the modernization of health recordkeeping.

Streamlining Drug & Device Requirements

Three Food and Drug Administration (FDA) proposed rules would standardize the electronic submission of clinical study data, medical device registrations, and adverse event reports. These rules will enable the FDA to more quickly and efficiently process and review information submitted, furthering their ability to both better protect the public safety and more rapidly advance new innovations to the market.

HHS—Office of the Secretary (OS)

PROPOSED RULE STAGE

42. STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION; MODIFICATIONS TO THE HIPAA PRIVACY RULE UNDER THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 111–5, secs 13400 to 13410

CFR Citation:

45 CFR 160; 45 CFR 164

Legal Deadline:

NPRM, Statutory, February 17, 2010.

Abstract:

The Department of Health and Human Services Office for Civil Rights will issue rules to modify the HIPAA Privacy Rule as necessary to implement the accounting provisions of Section 13405(c) of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Statement of Need:

The Office for Civil Rights will issue rules to modify the HIPAA Privacy rule to implement the privacy provisions in sections 13400-13410 of the Health Information technology for economic and clinical health Act (Title XIII of division a of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5). these regulations will improve the privacy and security protection of health information.

Summary of Legal Basis:

Subtitle D of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) requires the Office for Civil Rights to modify certain provisions of the HIPAA Privacy and Security Rules to implement sections 13400-13410 of the Act.

Alternatives:

The Office for Civil Rights is statutorily mandated to make modifications to the HIPAA Privacy and Security Rules to implement the privacy provisions at sections 13400-13410 of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Anticipated Cost and Benefits:

These modifications to the HIPAA Privacy Rule are intended to benefit health care consumers by strengthening the privacy and security protections that govern how their health information is used and disclosed by HIPAA covered entities and their business associates. The Agency believes that there may be costs associated with the regulations that will affect HIPAA covered entities and their business associates. These may include costs to redraft existing business associate contracts as well as for the training on new policies and procedures as a result of these regulations.

Timetable:

Action	Date	FR Cite
NPRM	12/00/09	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Andra Wicks
Department of Health and Human Services
200 Independence Avenue SW.
Washington, DC 20201
Phone: 202 205–2292
Fax: 202 205–4786
Email: andra.wicks@hhs.gov

RIN: 0991–AB57

HHS—OS

FINAL RULE STAGE

43. ● HEALTH INFORMATION TECHNOLOGY: INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA FOR ELECTRONIC HEALTH RECORD TECHNOLOGY (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

42 USC 300jj–14

CFR Citation:

45 CFR 170

Legal Deadline:

Other, Statutory, December 31, 2009, Interim final rule.

Abstract:

The Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology, will issue an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 3004(b)(1) of the Public Health Service Act.

Statement of Need:

This interim final rule represents the first round of what will be an incremental approach to adopting standards, implementation specifications, and certification criteria for health information technology. The certification criteria adopted in this initial set establish the technical capabilities and related standards that certified electronic health record (EHR) technology will need to include in support of the Medicare and Medicaid EHR Incentive Programs.

Summary of Legal Basis:

Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria by 12/31/09. This interim final rule is being published to meet this requirement.

Alternatives:

No alternatives are available because the issuance of this regulation is required by statute.

Anticipated Cost and Benefits:

We anticipate that there will be costs incurred as a result of the interim final rule to prepare health information technology for certification.

Benefits include improved interoperability and increased health information technology adoption.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/09	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Agency Contact:

Steven Posnack
Policy Analyst
Department of Health and Human Services
Office of the Secretary
Office of the National Coordinator for Health Information Technology
200 Independence Avenue SW
Washington, DC 20201
Phone: 202 690–7151

RIN: 0991–AB58

HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

44. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

21 USC 355; 21 USC 371; 42 USC 262

CFR Citation:

21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96

Legal Deadline:

None

Abstract:

The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive.

Statement of Need:

Before a drug is approved for marketing, FDA must determine that the drug is safe and effective for its intended use. This determination is based in part on clinical study data and bioequivalence data that are submitted as part of the marketing application. Study data submitted to FDA in electronic format have generally been more efficient to process and review.

FDA's proposed rule would require the submission of study data in a standardized electronic format. Electronic submission of study data would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive data more efficiently. Standardization would also enhance the ability to share study data and communicate results. Investigators and industry would benefit from the use of standards throughout the lifecycle of a study—in data collection, reporting, and analysis. The proposal would work in concert with ongoing agency and national initiatives to support increased use of electronic technology as a means to improve patient safety and enhance health care delivery.

Summary of Legal Basis:

Our legal authority to amend our regulations governing the submission and format of clinical study data and bioequivalence data for human drugs and biologics derives from sections 505 and 701 of the Act (U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262).

Alternatives:

FDA considered issuing a guidance document outlining the electronic submission and the standardization of study data, but not requiring electronic submission of the data in the standardized format. This alternative was rejected because the agency would not fully benefit from standardization until it became the industry standard, which could take up to 20 years.

We also considered a number of different implementation scenarios, from shorter to longer time-periods. The 2-year time-period was selected because the agency believes it would provide ample time for applicants to comply without too long a delay in the effective date. A longer time-period would delay the benefit from the increased efficiencies, such as standardization of review tools across applications, and the incremental cost savings to industry would be small.

Anticipated Cost and Benefits:

Standardization of clinical data structure, terminology, and code sets will increase the efficiency of the agency review process. FDA estimates that the costs to industry resulting from the proposal would include some one-time costs and possibly some annual recurring costs. One-time costs would include, among other things, the cost of converting data to standard structures, terminology, and cost sets (i.e., purchase of software to convert data); the cost of submitting electronic data (i.e., purchase of file transfer programs); and the cost of installing and validating the software and training personnel. Additional annual recurring costs may result from software purchases and licensing agreements for use of proprietary terminologies.

The proposal could result in many long-term benefits for industry, including improved patient safety through faster, more efficient, comprehensive, and accurate data review, as well as enhanced communication among sponsors and clinicians.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	06/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Martha Nguyen
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Bldg. 51, Room 6224
Silver Spring, MD 20993–0002
Phone: 301 796–3471
Fax: 301 847–8440
Email: martha.nguyen@fda.hhs.gov

RIN: 0910–AC52

HHS—FDA

45. ELECTRONIC REGISTRATION AND LISTING FOR DEVICES

Priority:

Other Significant

Legal Authority:

PL 110–85; PL 107–188, sec 321; PL 107–250, sec 207; 21 USC 360(a) through 360(j); 21 USC 360(p)

CFR Citation:

21 CFR 807

Legal Deadline:

None

Abstract:

FDA is proposing to amend the medical device establishment registration and listing regulations at 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Federal Food, Drug, and Cosmetic Act (the Act). Section 510(p) was added to the Act by section 207 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and later amended in September 2007 by section 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA). This proposed rule would require domestic and foreign device establishments to submit registration and listing data electronically via the Internet using FDA's Unified Registration and Listing System. This proposed rule would convert registration and listing to a paperless process. However, for those companies that do not have access to the Web, FDA would offer an avenue by which they can register, list, and update information with a paper submission. The proposed rule also would amend part 807 to reflect the timeframes for device establishment registration and listing established by sections 222 and 223 of FDAAA, and to reflect the requirement in section 510(i) of the Act, as amended by section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act), that foreign establishments provide FDA with additional pieces of information as part of their registration.

Statement of Need:

FDA is proposing to amend the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Act, which was added by section 207 of MDUFMA and later amended by section 224 of FDAAA. FDA also is proposing to amend 21 CFR part 807 to reflect the requirements in section 321 of the BT Act for foreign establishments to furnish additional information as part of their registration. This proposed rule would improve FDA's device establishment registration and listing system and utilize the latest technology in the collection of this information.

Summary of Legal Basis:

The statutory basis for our authority includes sections 510(a) through (j), 510(p), 701, 801, and 903 of the Act.

Alternatives:

The alternatives to this rulemaking include not updating the registration and listing regulations. Because of the new FDAAA statutory requirements, and the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative.

Anticipated Cost and Benefits:

The Agency believes that there may be some one-time costs associated with the rulemaking, which involve resource costs of familiarizing users with the electronic system. Recurring costs related to submission of the information by domestic firms would probably remain the same or decrease because a paper submission and postage is not required. There might be some increase in the financial burden on foreign firms since they will have to supply additional registration information as required by section 321 of the BT Act.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	09/00/10	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:

Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO–66 Room 4436
Silver Spring, MD 20993
Phone: 301 796–5739
Fax: 301 847–8144
Email: myrna.hanna@fda.hhs.gov

RIN: 0910–AF88

HHS—FDA

46. ● PRODUCE SAFETY REGULATION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 342; 21 USC 371; 42 USC 264

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The Food and Drug Administration is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce. The proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAPs Guide). The proposed rule also will reflect comments received on the agency's 1998 update of its GAPs guide and its July 2009 draft commodity specific

guidances for tomatoes, leafy greens, and melons. Although the proposed rule will be based on recommendations that are included in the GAPs guide, it does not make the entire guidance mandatory. FDA's proposed rule would, however, set out clear standards for implementation of modern preventive controls. The proposed rule also would emphasize the importance of environmental assessments to identify hazards and possible pathways of contamination and provide examples of risk reduction practices recognizing that operators must tailor their preventive controls to particular hazards and conditions affecting their operations. The requirements of the proposed rule would be scale appropriate and commensurate with the relative risks and complexity of individual operation. FDA intends to issue guidance after the proposed rule is finalized to assist industry in complying with the requirements of the new regulation.

Statement of Need:

FDA has determined that enforceable standards (as opposed to voluntary recommendations) for the production and packing of fresh produce are necessary to ensure best practices are commonly adopted.

Summary of Legal Basis:

FDA's legal basis derives in part from sections 402(a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(4) and 371(a)). The agency has promulgated regulations that respond to a number of the provisions of the 1986 amendments. This final rule would address additional provisions of these amendments.

Alternatives:

An alternative to this rulemaking would be to update FDA's 1998 GAPs Guide. However, even though the 1998 guidance has been well received and widely adopted, outbreaks associated with fresh produce continue. Outbreak investigations also continue to observe conditions and practices that are not consistent with the voluntary recommendations. FDA believes a regulation containing clear, enforceable standards would be more effective in ensuring best practices are widely adopted.

Anticipated Cost and Benefits:

FDA estimates that the costs to more than 300,000 domestic and foreign producers and packers of fresh produce from the proposal would include one-time costs (e.g., new tools and equipment) and recurring costs (e.g., monitoring, training, recordkeeping). FDA anticipates that the benefits would be a reduction in foodborne illness and deaths associated with fresh produce. Monetized estimates of costs and benefits are not available at this time.

Risks:

This regulation would directly and materially advance the Federal Government's substantial interest in reducing the risks for illness and death associated with foodborne infections resulting from the consumption of contaminated fresh produce. Less restrictive and less comprehensive approaches have not been effective in reducing the problems addressed by this regulation. FDA anticipates that the regulation would lead to a significant decrease in foodborne illness associated with fresh produce in the U.S.

Timetable:

Action	Date	FR Cite
NPRM	10/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

Undetermined

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:

Samir Assar
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740
Phone: 301 436–1636
Email: samir.assar@fda.hhs.gov

RIN: 0910–AG35

HHS—FDA

47. ● MODERNIZATION OF THE CURRENT FOOD GOOD MANUFACTURING PRACTICES REGULATION

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 342; 21 USC 371; 42 USC 264

CFR Citation:

21 CFR 110

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to amend its current good manufacturing practices (CGMP) regulations (21 CFR part 110) for manufacturing, packing, or holding human food. This proposed rule would require food facilities to address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces. The proposed rule also would require food facilities to develop and implement preventive control systems. FDA is taking this action to better address changes that have occurred in the food industry and thereby protect public health.

Statement of Need:

FDA last updated its food CGMP regulations for manufacturing, packing or holding of human food in 1986. Modernizing these food CGMP regulations to more explicitly address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces, as well as risk-based preventive controls, would be a critical step in raising the standards for food production and distribution. By amending 21 CFR 110 to modernize good manufacturing practices, the agency could focus the attention of food processors on measures that have been proven to significantly reduce the risk of food-borne illness. An amended regulation also would allow the agency to better focus its regulatory efforts on ensuring industry compliance with controls that have a significant food safety impact.

Summary of Legal Basis:

FDA's legal authority to amend its CGMP regulations derives in part from sections 402(a)(3), (a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic

Act (the Act) (21 U.S.C. 342(a)(3), (a)(4), and 371(a)). Under section 402(a)(3) of the Act, a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Under section 402(a)(4), a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the Act, FDA is authorized to issue regulations for the efficient enforcement of the Act. FDA's legal basis also derives from section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which gives FDA authority to promulgate regulations to control the spread of communicable disease.

Alternatives:

An alternative to this rulemaking is not to update the CGMP regulations, and instead to issue guidance on best practices regarding environmental pathogens, food allergens, mandatory employee training, sanitation of food contact surfaces, and risk-based preventive controls. However, guidance is voluntary and unenforceable. FDA believes a regulation containing clear, enforceable standards would be more effective in ensuring protection of public health.

Anticipated Cost and Benefits:

FDA estimates that the costs from the proposal to domestic and foreign producers and packers of processed foods would include new one-time costs (e.g., adoption of written food safety plans, setting up training programs, implementing allergen controls, and purchasing new tools and equipment) and recurring costs (e.g., auditing and monitoring suppliers of sensitive raw materials and ingredients, training employees, and completing and maintaining records used throughout the facility). FDA anticipates that the benefits would be a reduced risk of foodborne illness and deaths from processed foods and from a reduction in the number of safety related recalls.

Risks:

This regulation will directly and materially advance the federal government's substantial interest in reducing the risks for illness and death associated with foodborne infections. Less restrictive and less comprehensive approaches have not been effective in reducing the problems addressed by this regulation. The regulation will lead to a significant decrease in foodborne illness in the U.S.

Timetable:

Action	Date	FR Cite
NPRM	10/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

Undetermined

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:

Paul South
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS–317)
Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740
Phone: 301 436–1640
Email: paul.south@fda.hhs.gov

RIN: 0910–AG36

HHS—FDA

FINAL RULE STAGE

48. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS; AND QUALITY FACTORS

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 350a; 21 USC 371; . . .

CFR Citation:

21 CFR 106 and 107

Legal Deadline:

None

Abstract:

The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003. The comment period was reopened on August 1, 2006, to end on September 15, 2006.

Statement of Need:

The Food and Drug Administration (FDA) is revising its infant formula regulations in 21 CFR Parts 106 and 107 to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Summary of Legal Basis:

The Infant Formula Act of 1980 (the 1980 act) (Pub. L. 96-359) amended the Federal Food, Drug, and Cosmetic Act (the act) to include § 412 (21 U.S.C. 350a). This law is intended to improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. In 1982, FDA adopted infant formula recall procedures in subpart D of 21 CFR part 107 of its regulations (47 FR 18832, April 30, 1982), and infant formula quality control procedures in subpart B of 21 CFR Part 106 (47 FR 17016, April 20, 1982). In 1985, FDA further implemented the 1980 act by establishing subparts B, C, and D in 21 CFR Part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant formula, respectively (50 FR 1833, January 14, 1985; 50 FR 48183, November 22, 1985; and 50 FR 45106, October 30, 1985).

In 1986, Congress, as part of the Anti-Drug Abuse Act of 1986 (PL 99-570) (the 1986 amendments), amended § 412 of the act to address concerns that had been expressed by Congress and consumers about the 1980 act and its implementation related to the

sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. The 1986 amendments: (1) state that an infant formula is deemed to be adulterated if it fails to provide certain required nutrients, fails to meet quality factor requirements established by the Secretary (and, by delegation, FDA), or if it is not processed in compliance with the CGMP and quality control procedures established by the Secretary; (2) require that the Secretary issue regulations establishing requirements for quality factors and CGMP, including quality control procedures; (3) require that infant formula manufacturers regularly audit their operations to ensure that those operations comply with CGMP and quality control procedure regulations; (4) expand the circumstances in which firms must make a submission to the agency to include when there is a major change in an infant formula or a change that may affect whether the formula is adulterated; (5) specify the nutrient quality control testing that must be done on each batch of infant formula; (6) modify the infant formula recall requirements; and (7) give the Secretary authority to establish requirements for retention of records, including records necessary to demonstrate compliance with CGMP and quality control procedures. In 1989, the agency implemented the provisions on recalls (sections 412(f) and (g) of the act) by establishing subpart E in 21 CFR part 107 (54 FR 4006, January 27, 1989). In 1991, the agency implemented the provisions on record and record retention requirements by revising 21 CFR 106.100 (56 FR 66566, December 24, 1991).

The agency has already promulgated regulations that respond to a number of the provisions of the 1986 amendments. The final rule would address additional provisions of these amendments.

Alternatives:

The 1986 amendments require the Secretary (and, by delegation, FDA) to establish, by regulation, requirements for quality factors and CGMPs, including quality control procedures. Therefore, there are no alternatives to rulemaking.

Anticipated Cost and Benefits:

FDA estimates that the costs from the final rule to producers of infant formula would include first year and recurring costs (e.g., administrative costs, implementation of quality controls, records, audit plans and assurances of quality factors in new infant formulas). FDA anticipates that the primary benefits would be a reduced risk of illness due to Cronobacter sakazakii and Salmonella spp in infant formula. Additional benefits stem from the quality factors requirements that would assure the healthy growth of infants consuming infant formula. Monetized estimates of costs and benefits for this final rule are not available at this time. The analysis for the proposed rule estimated costs of less than $1 million per year. FDA was not able to quantify benefits in the analysis for the proposed rule.

Risks:

Special controls for infant formula manufacturing are especially important because infant formula, particularly powdered infant formula, is an ideal medium for bacterial growth and because infants are at high risk of foodborne illness because of their immature immune systems. In addition, quality factors are of critical need to assure that the infant formula supports healthy growth in the first months of life when infant formula may be an infant's sole source of nutrition. The provisions of this rule will address weaknesses in production that may allow contamination of infant formula, including, contamination with C. sakazakii and Salmonella spp which can lead to serious illness with devastating sequelae and/or death. The provisions would also assure that new infant formulas support healthy growth in infants.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End	12/06/96	
NPRM Comment Period Reopened	04/28/03	68 FR 22341
NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
NPRM Comment Period Reopened	08/01/06	71 FR 43392
NPRM Comment Period End	09/15/06	
Final Action	10/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:

Benson Silverman
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS–850)
5100 Paint Branch Parkway
College Park, MD 20740
Phone: 301 436–1459
Email: benson.silverman@fda.hhs.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF27

HHS—FDA

49. MEDICAL DEVICE REPORTING; ELECTRONIC SUBMISSION REQUIREMENTS

Priority:

Other Significant

Legal Authority:

21 USC 352; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

CFR Citation:

21 CFR 803

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to amend its postmarket medical device reporting regulations to require that manufacturers, importers, and user facilities submit mandatory reports of medical device adverse events to the Agency in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.

Statement of Need:

The final rule would require user facilities and medical device manufacturers and importers to submit medical device adverse event reports in electronic format instead of using a paper form. FDA is taking this action to improve its adverse event reporting program by enabling it to more quickly receive and process these reports.

Summary of Legal Basis:

The Agency has legal authority under section 519 of the Federal Food, Drug, and Cosmetic Act to require adverse event reports. The proposed rule would require manufacturers, importers, and user facilities to change their procedures to send reports of medical device adverse events to FDA in electronic format instead of using a hard copy form.

Alternatives:

The alternatives to this rulemaking include not updating the medical device reporting requirements and not requiring submission of this information in electronic format. For over 20 years, medical device manufacturers, importers, and user facilities have sent adverse event reports to FDA on paper forms. Processing paper forms is a time-consuming and expensive process. FDA believes this rulemaking is the preferable alternative.

Anticipated Cost and Benefits:

The principal benefit would be to public health because the increased speed in the processing and analysis of the more than 200,000 medical device reports currently submitted annually on paper. In addition, requiring electronic submission would reduce FDA annual operating costs by $1.25 million.

The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from $58.6 million to $79.7 million. Annually recurring costs totaled $8.5 million and included maintenance of electronic submission capabilities, including renewing the electronic certificate, and for some firms the incremental cost to maintain high-speed internet access.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	08/21/09	74 FR 42310
NPRM Comment Period End	11/19/09	
Final Action	09/00/10	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:

Myrna Hanna
Regulations Staff
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO–66 Room 4436
Silver Spring, MD 20993
Phone: 301 796–5739
Fax: 301 847–8144
Email: myrna.hanna@fda.hhs.gov

RIN: 0910–AF86

HHS—FDA

50. ● REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

Legal Authority:

21 USC 301 et seq., The Federal Food, Drug, and Cosmetic Act; PL 111–31, Family Smoking Prevention and Tobacco Control Act

CFR Citation:

Not Yet Determined

Legal Deadline:

Final, Statutory, March 22, 2010, Public Law 111–30 sections 6(c)(1) and 102(a)(1).

Family Smoking Prevention and Tobacco Control Act §§ 6(c)(1) and 102(a)(1) require publication of this final rule within 270 days of enactment.

Abstract:

This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing section 102 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). FSPTCA sections 102 and 6(c)(1) require the Secretary to publish, within 270 days of enactment, a final rule regarding cigarettes and smokeless tobacco. This final rule must be identical, except for several changes identified in section 102(a)(2) of FSPTCA, to part 897 of the regulations promulgated by the Secretary of HHS in the August 28, 1996 issue of the Federal Register (61 FR 44396).

This final rule prohibits the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits, with limited exception, free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. The rule also prohibits the sale or distribution of brand-identified promotional, non-tobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name.

Statement of Need:

FDA is issuing this regulation as required in section 102 of FSPTCA.

Summary of Legal Basis:

The legal authority to issue this regulation includes section 102 of FSPTCA.

Alternatives:

FDA's statutory requirement to issue this rule, in its current form, does not provide for the consideration of any alternatives.

Anticipated Cost and Benefits:

Congress has recognized that tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.

Based on FDA's prior analysis of a similar rule, implementing nearly

identical provisions (61 FR 44396), the Food and Drug Administration (FDA) believes this rulemaking will have a significant economic impact.

Costs associated with this rulemaking will include one-time costs to manufacturers to remove prohibited point-of-sale promotional items and self-service displays. Most costs to retail establishments are attributable to the new labor costs associated with the self-service restrictions, costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers. There are also costs seen by consumers in delay in checkout lines. Distributional and transitional costs are also expected.

Risks:

Congress has found that these regulations will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

Timetable:

Action	Date	FR Cite
Final Rule	03/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Philip R. Desjardins
Department of Health and Human Services
Food and Drug Administration
WO66, Room 5449
10903 New Hampshire
Silver Spring, MD 20993
Phone: 301 796–5683
Email: philip.desjardins@fda.hhs.gov

RIN: 0910–AG33

HHS—Centers for Medicare & Medicaid Services (CMS)

PROPOSED RULE STAGE

51. ● ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAM (CMS–0033–P)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 111–5 (The American Recovery and Reinvestment Act of 2009, Title IV of Division B, Medicare and Medicaid Health Information Technology)

CFR Citation:

Not Yet Determined

Legal Deadline:

Other, Statutory, October 1, 2010, Date can start incentive payments to hospitals (Medicare).

Other, Statutory, January 1, 2011, Date can start incentive payments to eligible professionals (Medicare).

Establishes policies and procedures required before the incentive program can begin. Additionally supplemental payments are available in 2011 and 2012. If eligible professionals and hospitals are not meaningful Electronic Health Record users by 2015 there will be a Medicare payment adjustment imposed.

Abstract:

The Medicare and Medicaid Health IT provisions in the American Recovery and Reinvestment Act of 2009 promote the adoption and meaningful use of certified electronic health records (EHRs). The Recovery Act authorized incentive payments for eligible professionals (EPS) and hospitals participating in Medicare and Medicaid for becoming meaningful users of certified EHRs. The law established maximum annual incentive amounts and includes Medicare penalties for failing to meaningfully use EHRs beginning in 2015 for professionals and hospitals that fail to adopt certified EHRs.

Statement of Need:

This rule would implement provisions of the American Recovery and Reinvestment Act of 2009 (Recovery Act) that authorizes incentive payments to EPS and eligible hospitals participating in the Medicare and Medicaid programs for adopting and becoming meaningful users of certified EHR technology.

Summary of Legal Basis:

Title IV of Division B of the Recovery Act includes provisions to promote the adoption of interoperable health information technology (HIT) to promote the meaningful use of health information technology to improve the quality and value of American health care. These provisions together with Title XIII of Division A of the Recovery Act may be cited as the ''Health Information Technology for Economic and Clinical Health Act'' or the ''HITECH Act''. CMS is charged with developing the incentive programs outlined in Division B, Title IV of the HITECH Act.

Alternatives:

There are no alternatives; this is a statutory requirement.

Anticipated Cost and Benefits:

Under Medicare, payment adjustments will be made starting in 2015 if EPs and eligible hospitals are not meaningful users of certified EHR technology. The benefits of the adoption of HIT are difficult to quantify. There is the potential of reduced medical costs through efficiency improvements. Additionally, HIT could help prevent medical errors and adverse drug interactions.

Risks:

If this rule is not published, CMS will be unable to pay incentives for the adoption and meaningful use of EHRs.

Timetable:

Action	Date	FR Cite
NPRM	12/00/09	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State

Federalism:

Undetermined

Agency Contact:

Elizabeth S. Holland
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop S2–26–17
7500 Security Blvd.
Baltimore, MD 21244
Phone: 410 786–1309
Email: elizabeth.holland@cms.hhs.gov

Related RIN: Related to 0991–AB58

RIN: 0938–AP78

HHS—CMS

52. ● REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND PART B FOR CY 2011 (CMS–1503–P)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

Social Security Act, sec 1102; Social Security Act, sec 1871

CFR Citation:

42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426

Legal Deadline:

Final, Statutory, November 1, 2010.

Abstract:

This major proposed rule would revise payment polices under the physician fee schedule, as well, as other policy changes to payment under Part B for CY 2011. (The statute requires the proposed and subsequent final rule publish by 11/1/10.)

Statement of Need:

The statute requires that we establish each year, by regulation, payment amounts for all physicians' services furnished in all fee schedule areas. This major proposed rule would make changes affecting Medicare Part B payment to physicians and other Part B suppliers.

The final rule has a statutory publication date of November 1, 2010, an implementation date of January 1, 2011.

Summary of Legal Basis:

Section 1848 of the Social Security Act (the Act) establishes the payment for physician services provided under Medicare. Section 1848 of the Act imposes a deadline of no later than November 1 for publication of the final physician fee schedule rule.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

Total expenditures will be adjusted for CY 2011.

Risks:

If this regulation is not published timely, physician services will not be paid appropriately.

Timetable:

Action	Date	FR Cite
NPRM	06/00/10	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Cassandra Black
Director, Division of Practitoner Services
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop C4–01–26
7500 Security Blvd
Baltimore, MD 21244
Phone: 410 786–4545
Email: cassandra.black@cms.hhs gov

RIN: 0938–AP79

HHS—CMS

53. ● PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND FY 2011 RATES AND TO THE LONG–TERM CARE HOSPITAL PPS AND RY 2011 RATES (CMS–1498–P)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

Sec 1886(d) of the Social Security Act

CFR Citation:

42 CFR 412

Legal Deadline:

NPRM, Statutory, April 1, 2010.

Final, Statutory, August 1, 2010.

Abstract:

Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2011 Rates and to the Long Term Care Hospital PPS and RY 2011 Rates

Statement of Need:

CMS annually revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. Also, CMS annually updates the payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). The proposed rule solicits comments on the proposed IPPS and LTCH payment rates and new policies. CMS will issue a final rule containing the payment rates for the 2011 IPPS and LTCHs at least 60 days before October 1, 2010.

Summary of Legal Basis:

The Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. The Act requires the Secretary to pay for the capital-related costs of hospital inpatient and Long Term Care stays under a prospective payment system (PPS). Under these PPSs, Medicare payment for hospital inpatient and Long Term Care operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. These changes would be applicable to services furnished on or after October 1, 2010.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

Total expenditures will be adjusted for FY 2011.

Risks:

If this regulation is not published timely, inpatient hospital and LTCH

services will not be paid appropriately beginning October 1, 2010

Timetable:

Action	Date	FR Cite
NPRM	04/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Tiffany Swygert
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mailstop C4–25–11
7500 Security Blvd.
Baltimore, MD 21244
Phone: 410 786–4642
Email: tiffany.swygert@cms.hhs.gov

RIN: 0938–AP80

HHS—CMS

54. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2011 (CMS–1504–P)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

Sec 1833 of the Social Security Act

CFR Citation:

42 CFR 410 to 413; 42 CFR 416

Legal Deadline:

Final, Statutory, November 1, 2010.

Abstract:

This major proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also proposes changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1 annually. (The proposed and subsequent final rule must publish by 11/1/10.)

Statement of Need:

Medicare pays over 4,200 hospitals for outpatient department services under the hospital outpatient prospective payment system (OPPS). The OPPS is based on groups of clinically similar services called ambulatory payment classification groups (APCs). CMS annually revises the APC payment amounts based on claims data, proposes new payment polices, and updates the payments for inflation using the hospital operating market basket. The proposed rule solicits comments on the proposed OPPS payment rates and new policies. This rule does not impact payments to critical access hospitals as they are not paid under the OPPS. Medicare pays roughly 5,000 Ambulatory Surgical Centers (ASCs) under the ASC payment system. CMS annually revises the payment under the ASC payment system, proposes new policies, and updates payments for inflation using the Consumer Price Index for All Urban Consumers (CPI-U). CMS will issue a final rule containing the payment rates for the 2011 OPPS and ASC payment system at least 60 days before January 1, 2011.

Summary of Legal Basis:

Section 1833 of the Social Security Act establishes Medicare payment for hospital outpatient services. The final rule revises the Medicare hospital OPPS to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, the proposed and final rules describe changes to the outpatient APC system, relative payment weights, outlier adjustments, and other amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system as well as changes to the rates and services paid under the ASC payment system. These changes would be applicable to services furnished on or after January 1, 2011.

Alternatives:

None. This is a statutory requirement.

Anticipated Cost and Benefits:

Total expenditures will be adjusted for CY 2011.

Risks:

If this regulation is not published timely, outpatient hospital and ASC services will not be paid appropriately beginning January 1, 2011.

Timetable:

Action	Date	FR Cite
NPRM	06/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Federalism:

Undetermined

Agency Contact:

Alberta Dwived
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop C5–01–26
7500 Security Blvd,
Baltimore,, MD 21244
Phone: 410 786–0763
Email: alberta.dwived@cms.hhs.gov

RIN: 0938–AP82

HHS—CMS

FINAL RULE STAGE

55. HIPAA MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT OF 2008 AMENDMENTS (CMS–4140–IFC)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

Mental Health Parity and Addication Equity Act of 2008 (P.L.110–343)

CFR Citation:

45 CFR 146.136

Legal Deadline:

Final, Statutory, October 3, 2009, Interim final regulation.

Abstract:

This rule implements statutory changes to the Public Health Services Act (PHSA) affecting the group health insurance markets and non-federal governmental plans, made by the Mental Health Parity and Addiction Equity Act of 2008.

Statement of Need:

This rule is needed to implement MHPAEA, which expands the existing Mental Health parity law to include substance abuse disorders and to require parity for mental health and substance abuse disorder benefits in treatment limitations and financial requirements.

Summary of Legal Basis:

The Public Health Service Act and MHPAEA provide the authority to implement this rule.

Alternatives:

Since this is a statutory requirement, no alternatives were considered.

Anticipated Cost and Benefits:

Promulgation of this rule will provide greater access to mental health and substance abuse disorder treatments by requiring group health plans to provide better coverage for those treatments.

Risks:

This rule addresses the risk of individuals not being able to obtain necessary mental health and/or substance abuse disorder treatment because of limited health coverage for those treatments. By increasing access to treatment for mental health conditions and substance abuse disorders, this rule will also reduce the stigma experienced by millions of Americans who are afflicted with these conditions and allow them to remain in the workforce.

Timetable:

Action	Date	FR Cite
Request for Information	04/28/09	74 FR 19155
RFI Comment Period End	05/28/09	
Interim Final Rule	01/00/10	
Interim Final Rule Comment Period End	03/00/10	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Jim Mayhew
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410 786–9244
Email: jim.mayhew@cms.hhs.gov

Related RIN: Related to 1210–AB30, Related to 1545–BI70

RIN: 0938–AP65

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